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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,133	09/19/2003	Howard M. Johnson	UF-243XD1	7182

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,133	JOHNSON ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 20-35, drawn to a method of suppression or inhibition of allergen-specific IgE production by administering interferon tau is acknowledged. Applicant has further elected "oral" as the route of administration and "rhinitis" as the allergic condition in response to requirement for species election. The restriction requirement is made final. Claims 1-19 are cancelled. Claims 20, 22, 25, 26, 28, 29, 32 and 33 are amended. Thus, Claims 20-35 are considered.

Priority

2. Applicant's priority claim to 60/151026, filed 27 August 1999 and 09/648,864, filed 8/25/2000 is acknowledged. The Applicants are required to update the status priority application 09/648, 864 in the specification.

Information Disclosure Statement

3. Applicant's information disclosure statements filed 3/24/2004 has been considered in full.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using interferons and interferon chimeras, does not reasonably provide enablement for methods using biologically active

fragments of these molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant has described methods using interferons to reduce IgE levels, and methods are also known in the prior art (see below). However, applicant has not described methods using fragments of these molecules, nor has Applicant set forth the characteristics of such biologically active fragments so that one of skill in the art could predictably identify interferon fragments that could be used as claimed. Applicant has not described the properties or characteristics of the interferons that are required for activity. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of fragments potentially meeting the limitations of the claims when the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structures or conserved sequences are necessary for the claimed function, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

6. Claims 20-35 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has methods using interferons to decrease IgE levels and methods are also known in the art. However, the claims are drawn to methods using biologically active fragments, and thus encompass methods using molecules that vary substantially in length and also in

composition. There is no description of the required structural and functional features of the such fragments, or of the conserved regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what fragments would possess the same defining characteristics. Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of the claimed genus of methods using fragments of interferons.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 20-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20, 28 and 35 rejected as indefinite in the recitation of "to a person or animal in need of suppression of inhibition of allergen-specific IgE production". There is no definition in the specification of an "IgE-related condition". One of skill in the art would not be able to determine what conditions Applicant intended to encompass; IgE is presumable involved in some way in many different conditions. Claims 21-27 and 29-34 are rejected insofar as they are dependent on rejected claims 20 and 28.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 20 and 22-35 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by U.S. patent 5,906,816 (Soos et al., May 25, 1999)

The '816 patent teaches mammalian interferon tau in, for example, column 6, lines 36-67. The '816 patent teaches that it is useful for the treatment of autoimmune disease in, for example, column 5, lines 50-63, column 9, lines 64-67, column 10, lines 1-63, column 11, lines 5-55 and claims 1-11. Inhibition is discussed both in animal models and cells. Such treatment would inherently result in the suppression of IgE production, regardless of whether this suppression or the mechanism by which it was achieved was recognized. Thus the '816 patent anticipates the limitations of claims 20, 27, 28, 34 and 35. Any person suffering from an autoimmune disease who also suffered from allergy would be in need of such suppression and the limitations of claims 20, 23, 24, 30 and 36 are thus also anticipated. Use for treatment of allergic rhinitis is also specifically taught in column 5, lines 40-52. Thus, meeting the limitation of claims 24 and 31. Also disclosed is inhibition of T-cell proliferation, column 11, lines 5-15. In vitro administration, as claimed in claims 25 and 32, is taught in column 9, table 2. The route of administration including oral administration is described in column 15, lines 3-

13, thus meeting the limitation of claims 22 and 29. The composition of interferon tau, as claimed in claims 26 and 33 is taught in column 13, lines 55-65. Therefore, claims 20 and 22-35 are rejected as anticipated Soos et al. (U.S. patent 5,906,816).

11. Claims 20, 21, 27, 28, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Mujtaba et al. (Cellular Immunology, 1998, vol. 186, pages 94-102, R34 in PTO1449 of 3/24/2004).

Mujtaba et al. describe the inhibition MBP induced proliferation of B cells from EAE mice following the treatment interferon tau (abstract). Such treatment would inherently result in the suppression of IgE production, regardless of whether this suppression or the mechanism by which it was achieved was recognized, meeting the limitation of claims 20, 21, 28 and 35. The reference also teaches mammalian interferon tau (page 95, 1st paragraph), meeting the limitations of claims 27 and 34. Therefore claims 20, 21, 27, 28, 34 and 35 are rejected as being anticipated by Mujtaba et al. (Cellular Immunology, 1998, vol. 186, pages 94-102).

12. No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSS 07/05

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER